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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,484	12/29/2003	Darrell C. Conklin	97-72D1	9463

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,484	CONKLIN ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-2) on 9/28/2005 is acknowledged. The traversal is on the ground(s) that the Examiner has made a restriction between Groups 1-24 and Applicants assert that the Groups are closely related since they are all directed to antibodies that bind to Zcyto10 (IL-20) polypeptide sequence. However, contrary to Applicants arguments, a search for an antibody to the protein of amino acid sequence set forth in SEQ ID NO:2 would not necessarily reveal art to an antibody to the proteins of amino acid sequence set forth in SEQ ID NO:4, 19 and 34 which are variants and species variants of the Zcyto10 polypeptide. Therefore, there would be undue burden placed on the Examiner if Groups I-24 were to be considered in the same application, as the searches would not be co-extensive.

Therefore, an antibody to human Zcyto10 polypeptide of amino acid sequence set forth in SEQ ID NO:2, 12, 26, 14, 15, 16, 17 will be examined in the instant application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 encompassing an antibody to SEQ ID NO:2, 12, 26, 14, 15, 16, 17 will be examined in the instant application.

Specification

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "antibody to mammalian cytokine-like polypeptide-10".

2b. On page 9, lines 23-24, part of the specification is missing or has been inadvertently deleted. Appropriate correction is requested.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter.

Claim 1, as written, recite "an antibody" and does not sufficiently distinguish over the product that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim rejections-35 U.S.C. 101

4 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim is directed to an antibody to a cytokine-like polypeptide-10 (interleukin-20, Zcyto10) 176 amino acids in length. The invention encompassed by this claim has no apparent

or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published on 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated protein, but does not disclose a specific and substantial biological role of this protein or its significance. There is no biological activity, phenotype, disease or condition, or any other specific feature that is disclosed as being associated with the IL-20 polypeptide. The mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polypeptide without any information as to the specific properties of IL-20. Since significant further research would be required of a person skilled in the art to determine how the claimed polypeptide is involved in any activities, the asserted utilities are not substantial.

Furthermore, since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

The specification asserts several utilities for the polypeptide of SEQ ID NO:2, that are not necessarily related to its biological activities; however, none of these asserted utilities meets the three-pronged test of being credible, specific and substantial. Each will be addressed in turn:

1. *to produce variant polypeptides*. This asserted utility is not specific or substantial. Since the same assays can be performed with any polypeptide, the asserted utility is not specific to the claimed polypeptide (SEQ ID NO:2). Also, since the specification does not disclose how the variants of the polypeptide, such as molecules with 50%, 60% and 80% homology to SEQ ID NO:2, can be used, significant further research would be required of a person skilled in the art to determine how to use the claimed variants. Since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

2. *to produce antibodies against the polypeptides*. This asserted utility is not specific or substantial. Since antibodies can be made to any polypeptide, the asserted utility is not specific to the IL-20 polypeptide. Furthermore, the specification does not disclose how anti-IL-20 antibodies can be used, and therefore further significant research would be required on one skilled in the art to determine how to use the claimed antibodies. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

3. *to promote wound healing.* This asserted utility is not specific or substantial. The specification alleges that the IL-20 polypeptide plays a role in wound healing because the (expression level of RNA encoding the cyto10 protein in wounded skin was elevated two fold compared to that of the control sample and therefore the cyto10 protein can be applied to a wound or a burn to promote wound healing see page 34, lines 11-20; Example 4, pages 37-39). However, the specification does not disclose the role of cyto10 protein in wound healing or the result of applying cyto10 to a wound or a burn to promote wound healing. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

4. *to increase platelet count.* This asserted utility is not specific or substantial.
The experimental evidence presented in Example 8, page 42-43 and page 34, lines 24-27, of the specification is, neither convincing nor specific. The specification asserts that cyto10 affects haematopoiesis and increases platelet counts in both male and female mice treated with Zcyto10-

adenovirus compared to empty adenovirus control but decreases hematocrit and decreases spleen and liver weight in male mice. The specification and does not provide any evidence of cyto10 induced platelet increase. Therefore, since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

5. *in the treatment of disease.* The asserted utility is not specific or substantial.

The specification on page 31, lines 31-33 and page 32, lines 1-15, discloses that

"Zcyto10 polypeptides, agonists or antagonists thereof may be therapeutically useful in the regeneration of the gastrointestinal tract or oral cavity.

Zcyto10 polypeptides, agonists or antagonists thereof may be useful in the treatment of asthma and other diseases of the tracheobronchial tract, such as bronchitis and the like, by intervention in the cross-regulation of Th1 and Th2 lymphocytes, regulation of growth, differentiation and cytokine production of other inflammatory cellular mediators, such as eosinophils, mast cells, basophils, neutrophils and macrophages. Zcyto10 polypeptides, agonists or antagonists thereof may also modulate muscle tone in the tracheobronchial tract. Zcyto10 polypeptides can also be used to treat a number of skin conditions either systemically or locally when placed in an ointment or cream, for example eczema, psoriasis or dry skin conditions in general or as related skin attentions. Also the Zcyto10 polypeptide can be directly injected into muscle to treat muscle atrophy in the elderly, the sick or the bed-ridden.

The specification does not disclose any specific diseases or disorders associated with human cyto10. Furthermore, since many antibodies can and are used as therapeutic reagents, the asserted utility is not specific to the claimed antibody to Zcyto10 polypeptide. Since the asserted

utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

Claim rejections-35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed polynucleotide encoding the Zcyto7protein, therefore, there is no specific and substantial asserted utility or well established for the claimed polynucleotide encoding the Zcyto7 protein.

Claim rejections, 35 U.S.C. § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because it recites non-elected sequences.

Appropriate correction of the claim to recite only the elected sequence is required.

Conclusion

Claims 1-2 are rejected.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
October 31, 2005